

#### § 405.2164

(2) Make the protocol available to the patient to ensure safe and effective home use of EPO; and

(3) Through the amounts prescribed, ensure that the drug “on hand” at any time does not exceed a 2-month supply.

[43 FR 48953, Oct. 19, 1978, as amended at 51 FR 30362, Aug. 26, 1986; 57 FR 7134, Feb. 28, 1992; 59 FR 1284, Jan. 10, 1994; 59 FR 26958, May 25, 1994; 59 FR 46513, Sept. 8, 1994; 61 FR 19743, May 2, 1996]

#### § 405.2164 Conditions for coverage of special purpose renal dialysis facilities.

(a) A special purpose renal dialysis facility must comply with all conditions for coverage for renal dialysis facilities specified in §§ 405.2130 through 405.2164, with the exception of §§ 405.2134, and 405.2137 that relate to participation in the network activities and patient long-term programs.

(b) A special purpose renal dialysis facility must consult with a patient's physician to assure that care provided in the special purpose dialysis facility is consistent with the patient's long-term program and patient care plan required under § 405.2137.

(c) The period of approval for a special purpose renal dialysis facility may not exceed 8 calendar months in any calendar year.

(d) A special purpose renal dialysis facility may provide services only to those patients who would otherwise be unable to obtain treatments in the geographical areas served by the facility.

[48 FR 21283, May 11, 1983, as amended at 51 FR 30362, Aug. 26, 1986]

#### § 405.2170 Condition: Director of a renal transplantation center.

The renal transplantation center is under the general supervision of a qualified transplantation surgeon (§ 405.2102) or a qualified physician-director (§ 405.2102), who need not serve full time. This physician is responsible for planning, organizing, conducting, and directing the renal transplantation center and devotes sufficient time to carry out these responsibilities, which include but are not limited to the following:

(a) Participating in the selection of a suitable treatment modality for each patient.

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(b) Assuring adequate training, of nurses in the care of transplant patients.

(c) Assuring that tissue typing and organ procurement services are available either directly or under arrangement.

(d) Assuring that transplantation surgery is performed under the direct supervision of a qualified transplantation surgeon.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 51 FR 30362, Aug. 26, 1986; 59 FR 46514, Sept. 8, 1994]

#### § 405.2171 Condition: Minimal service requirements for a renal transplantation center.

Kidney transplantation is furnished directly by a hospital that is participating as a provider of services in the Medicare program and is approved by HCFA as a renal transplantation center. The renal transplantation center is under the overall direction of a hospital administrator and medical staff; if operated by an organizational subsidiary, it is under the direction of an administrator and medical staff member (or committee) who are directly responsible to the hospital administrator and medical staff, respectively. Patients are accepted for transplantation only on the order of a physician and their care continues under the supervision of a physician.

(a) *Standard: participation in recipient registry.* The renal transplantation center participates in a patient registry program with an OPO certified or recertified under part 485, subpart D of this chapter for patients who are awaiting cadaveric donor transplantation.

(b) *Standard: social services.* Social services are provided to patients and their families and are directed at supporting and maximizing the social functioning and adjustment of the patient. Social services are furnished by a qualified social worker (§ 405.2102) who has an employment or contractual relationship with the facility. The qualified social worker is responsible for conducting psychosocial evaluations, participating in team review of patient progress and recommending changes in treatment based on the patient's current psychosocial needs, providing